DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 20, 2015

C.R. Bard, Inc.
Mr. James Davis
Regulatory Affairs Specialist
Bard Access Systems, Inc.
605 North 5600 West
Salt Lake City, Utah 84116

Re: K150514
Trade/Device Name: Power-injectable Implantable Ports with Chronoflex® Polyurethane Catheters
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: October 22, 2015
Received: October 23, 2015

Dear Mr. Davis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang
-S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150514

Device Name
Power-Injectable Implantable Ports with ChronoFlex® Polyurethane Catheters

Indications for Use *(Describe)*
The PowerPort® implanted port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.

When used with a PowerLoc® safety infusion set, the PowerPort® device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/s.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K150514

510(k) Summary
21 CFR 807.92

Power-Injectable Implantable Ports with ChronoFlex® Polyurethane Catheters

General Provisions	Submitter Name: Address:	Bard Access Systems, Inc. 605 North 5600 West Salt Lake City, UT 84116
	Contact Person	James R. Davis Regulatory Affairs Specialist James.R.Davis@crbard.com 801.522.5000 ext 5456 801.522.5425
	Date of Preparation:	22 October 2015
Subject Device	Trade Name:	Power-Injectable Implantable Ports with ChronoFlex® Polyurethane Catheters
	Common/Usual Name:	Implanted Infusion Port & Catheter
	Classification Name:	Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
	Product Code:	LJT
	Regulation:	21 CFR 880.5965
Predicate Device	Trade Name:	PowerPort® ClearVUE® Slim Implantable Port
	Classification Name:	Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
	Premarket Notification:	K122899
	Manufacturer:	Bard Access Systems, Inc.
Reference Devices	Trade Name:	Titanium PowerPort® ISP Implanted Port with 6 Fr. ChronoFlex® Polyurethane Catheter
	Classification Name:	Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
	Premarket Notification:	K072549
	Manufacturer:	Bard Access Systems, Inc.
	Trade Name:	PowerPort® Polymeric Port with 8 F S/L ChronoFlex® Catheters
	Classification Name:	Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
	Premarket Notification:	K063377
	Manufacturer:	Bard Access Systems, Inc.

Reference Devices Justification	The references devices are provided because a bundled 510(k) submission is appropriate for the subject device since the scientific and regulatory issues are most efficiently addressed during one review. Additionally, the performance data is the same for the subject devices, only the General Hospital review branch is involved with the review process and the devices have the same indications for use.

Subject and Predicate Device Comparison

Attribute	SUBJECT DEVICE Power-Injectable Implantable Ports with ChronoFlex® Polyurethane Catheters	PREDICATE DEVICE PowerPort® ClearVUE® Slim Implantable Port (K122899)
Note	• **Bold red font** indicates a **difference between** the **subject device** and the current regulatory predicate baseline of the **predicate device**. • Plain type indicates that the attribute of the subject device is the same as that of the current regulatory baseline of the predicate device.	
Owner	Same	Bard Access Systems, Inc.
510(k) Status	Subject of this Premarket Notification	K122899 Concurrence Date: November 15th, 2012
Classification	Same	21 CFR 880.5965 – Class II LJT – Subcutaneous, implanted, intravascular infusion port and catheter
Intended Use	Same	Power-Injectable Implantable Ports are intended to be an implanted vascular access device designed to provide long-term, repeated access to the vascular system.
Indications for Use	Same	The PowerPort® implanted port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples. When used with a PowerLoc® safety infusion set, the PowerPort® device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/s.
Duration of Use	Same	Long term (>30 days)
Insertion Site	Same	Port is implanted subcutaneously with catheter tunneled and inserted in blood vessel
Catheter Tip Location	Same	Central venous system – lower 1/3 of superior *vena cava* preferred
Significant Device Dimensions	8 Fr. & 6 Fr. Catheter Surface Profilometry **RMS Value: ≤0.5µm**	8 Fr. & 6 Fr. Catheter Surface Profilometry N/A
Catheter Body Materials	Same	Polyurethane
Port Body Materials	Same	Polyetheretherketone (Body/Stem) Silicone (Suture Plugs)
Catheter Lock Materials	Same	Polycarbonate

Device Description	PowerPort® Implantable Ports are designed to provide repeated access to the vascular system without the need for repeated venipuncture or daily care of an external catheter. Long-Term Implantable Ports consist of a rigid housing and a self-sealing septum. The catheters used with infusion ports are essentially the same design as externalized, stand-alone intravascular catheters. Polyurethane catheters are attached to the port by the physician during implantation. PowerPort® Implantable Ports can be used for routine vascular access using a non-coring access needle. However, for power injection procedures, PowerPort® ports must be accessed with a Bard PowerLoc® Safety Infusion Set (SIS) to create a power-injectable system. The ChronoFlex® Polyurethane Catheters maintain an average root mean square catheter surface profilometry of less than 0.5µm.
Intended Use	Power-Injectable Implantable Ports are intended to be an implanted vascular access device designed to provide long-term, repeated access to the vascular system.
Indications for Use	The PowerPort® implanted port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples. When used with a PowerLoc® safety infusion set, the PowerPort® device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/s.
Technological Characteristics	The technological characteristics of the subject Power-Injectable Ports with ChronoFlex® Polyurethane Catheters are substantially equivalent with respect to design and function to those of the predicate devices.

Performance Tests	Verification and validation activities were designed and performed in accordance with Design Controls as per 21 CFR §820.30. The following guidance documents and standards in conjunction with in-house protocols were used to determine appropriate methods for evaluating the performance of the device: • FDA Guidance – *Guidance on 510(k) Submissions for Implanted Infusion Ports;* October, 1990 • FDA Guidance – *Guidance on 510(k) Submissions for Short-Term and Long-Term Intravascular Catheters,* March 16, 1990 • FDA Guidance – *General Considerations for Animal Studies for Cardiovascular Devices,* dated July 29,2010 • FDA Guidance – *Good Laboratory Practices Questions and Answers*, dated July, 2007 • FDA Guidance – *Bundling Multiple Devices or Multiple Indications in a single submission,* dated June 22, 2007 • FDA Guidance – *Establishing safety and compatibility of passive implants in the magnetic resonance environment,* dated August 21, 2008 • ISO 10555-1 Second Edition 2013-07-01, Sterile, Single-Use Intravascular Catheters, Part 1: General Requirements • ISO 10555-3 Second Edition 2013-06-15, *Sterile, Single-Use Intravascular Catheters, Part 3: Central Venous Catheters* • AAMI/ANSI/ISO 11135-1: 2007, *Sterilization of Healthcare Products – Ethylene Oxide* • AAMI/ANSI/ISO 10993-1:2009/(R) 2013, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*, and the FDA Modified ISO 10993 Test Profile • ISO 10993-7 Second Edition 2008-10-15, *Biological Evaluation for Medical Devices; Part 7 – Ethylene Oxide Sterilization Residuals* • AAMI/ANSI/ISO 11607:2006/(R)2010, *Packaging for Terminally Sterilized Medical Devices* • AAMI / ANSI ST72:2011: *Bacterial Endotoxins—Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing* • ASTM F2503-13 (2014), *Standard Practice for marketing Medical Devices and Other Items for Safety in the Magnetic Resonance (MR) Environment* The subject device met all pre-determined acceptance criteria and demonstrated substantial equivalence as compared to the predicate devices.
Testing Conclusion	The results of the testing performed demonstrate the subject device performance is substantially equivalent to the predicate device.
Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, and performance testing, the subject Power-Injectable Ports with ChronoFlex® Polyurethane Catheters meets the requirements that are considered sufficient for its intended use and demonstrates that the subject devices are substantially equivalent to the predicate devices cited.